



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy / Wholesaler Level

Date: 29 November 2022

EL (22)A/49

Our Ref: MDR 176-11/22

Dear Healthcare Professional,

Lucis Pharma Ltd

Oxycodone Hydrochloride 10mg/ml oral solution

PL 42176/0015

Batch No	Expiry Date	Pack Size	First Distributed
21050004	November 2023	120mL Bottle	15/07/2021
22080005	February 2025	120mL Bottle	13/10/2022

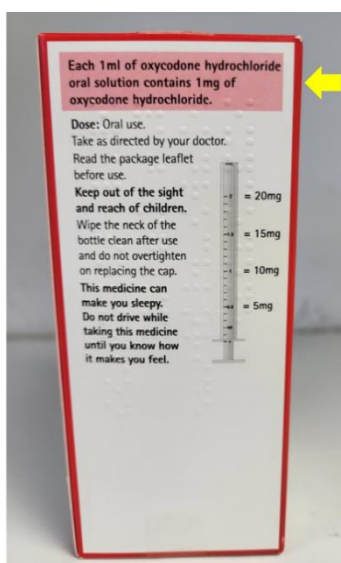
Active Pharmaceutical Ingredient: Oxycodone Hydrochloride

Brief description of the problem

Lucis Pharma Ltd has informed the MHRA that there is a typographical error with text on the rear side of the outer packaging for Oxycodone Hydrochloride 10mg/ml Oral Solution.

The text incorrectly states that: *'Each 1ml of oxycodone hydrochloride oral solution contains 1mg of oxycodone hydrochloride.'*

The **correct** text should state: *'Each 1ml of oxycodone hydrochloride oral solution contains 10mg of oxycodone hydrochloride.'*



The strength of the product is printed correctly on all other sides of the outer packaging, including the label on the bottle.



Medicines & Healthcare products
Regulatory Agency

Advice for healthcare professionals

Healthcare professionals should note that there is no risk to product quality and efficacy, therefore the affected batches are not being recalled.

Healthcare professionals should exercise caution when dispensing or supplying this product. Please refer to the correct information stated on the bottle label and in the Patient Information Leaflet inserted in the pack.

Advice for patients

This notification relates to a typographical error on the outer packaging of the product. The medicine itself is not affected and patients do not need to take any action.

Further Information

For medical information and stock control queries please contact: enquiries@lucispharma.co.uk

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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